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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,136	07/26/2001	Ricardo Rocha	S03357/1/US	8218

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,136	ROCHA ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-96* is/are pending in the application.

4a) Of the above claim(s) *77-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-76 and 87-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/27/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 77-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper submitted December 2, 2003.

Applicant's election without traverse of invention group II, now claims 72-96, and eplerenone and myocardial infarction as the species in Paper submitted December 3, 2003 is acknowledged.

The claims have been examined insofar as they read on the elected species.

Claim Objections

2. Claims 75 and 76 are objected to because of the following informalities: claim 75 and 76 recited the same compound with different names. It is suggested to use one name.

3. Claim 75, line 3 recite "(γ-lactone". It is appears to be a typo of "γ-lactone." Appropriate correction is required.

Claim Rejections 35 U.S.C. 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 72-76, 87-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Grob et al. (US 4,559,332). IDS

Grob et al. teaches a method of controlling hyperaldosteronism in human comprising administering a 20-spiroxanes, wherein eplerenone is a preferred compound. The daily effective amount is in the range of 5 mg to 200mg. See, particularly, column 1-3, column 15, lines 44-50, and the claims. Note patient take the medicine as instructed by Grob would have been inherently practice the claimed method, i.e., preventing myocardial infarction. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to treating or preventing a malady or disease with old and well known compounds or compositions. It is now well-settled law that administering compounds inherently possessing a therapeutic utility anticipates claims directed to such therapeutic use. Arguments that such therapeutic use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance

the proffered claims from the anticipated therapeutic utility, renders such claims anticipated by the prior inherent use.

6. Claims 72-76 and 87-96 are rejected under 35 U.S.C. 102(e) as being anticipated by Thosar et al. (US 6,410,054).

7. Thosar et al. teaches a composition comprises eplerenone as the active ingredients for treating myocardial infarction. See, particularly, column 3, lines 19-34, column 4, lines 4 to column 5, line 56, and the claims.

Claim Rejections 35 U.S. C 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 72-76 and 87-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grob et al. (US 4,559,332) in view of MacLaughlan et al. (WO 96/24358).

Grob et al. teaches a method of controlling hyperaldosteronism in human comprising administering a 20-spiroxanes, which is an aldosterone antagonist, wherein eplerenone is a preferred compound. The daily effective amount is in the range of 5 mg to 200mg. See, particularly, column 1-3, column 15, lines 44-50, and the claims.

Grob does not teach expressly teaches that the method may be employed for treating myocardial infarction.

However, MacLaughlen teaches that aldosterone antagonist is known to be useful for treating circulatory disorders, particularly for treating or retarding the development of congestive heart failure. See, particularly, the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ Grob's method for treating myocardial infarction.

A person of ordinary skill in the art would have been motivated to employ Grob's method for treating myocardial infarction because aldosterone antagonist are known to be useful for treating or retarding the development of congestive heart failure. Note, myocardial infarction is an underline etiology of congestive heart failure. Further, the optimization of a result effective parameter, e.g., effective, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

10. Claims 72-76 and 87-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thosar et al. (US 6,410,054).

11. Thosar et al. teaches a composition comprises eplerenone as the active ingredients. Thosar further teaches that the composition are useful for the prophylaxis and treatment of various cardiovascular disorders, including myocardial infarction. The daily amount of eplerenone is about 0.33 to 2.67 mg/kg body weight. See, particularly, column 3, lines 19-34, column 4, lines 4 to column 5, line 56, and the claims.

Thosar et al. does not teach expressly for treating myocardial infarction. However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the composition disclosed by Thosar et al for

prophylaxis or treatment of myocardial infarction because the composition are known to be useful for such purpose. Further, the optimization of a result effective parameter, e.g., effective, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Primary Examiner

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang

February 14, 2004